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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,267	04/23/2001	Carol L. Novak	2001P07304 US	3216

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Siemens Corporation
Intellectual Property Department
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EXAMINER

EDWARDS, PATRICK L

ART UNIT PAPER NUMBER

2621

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/840,267

Applicant(s)

NOVAK ET AL.

Examiner

Patrick L Edwards

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34 is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-13, 18-25 and 31-33 is/are rejected.
- 7) ☒ Claim(s) 9, 14-17 and 26-30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The response received on July 6, 2004 has been placed in the file and was considered by the examiner. An action on the merits follows.

Response to Arguments

2. The applicant's arguments, filed on July 6, 2004, have been fully considered. A response to these arguments is provided below.

Specification Objections

Summary of Argument: Applicant has amended the specification to update the status of the applications.

Examiner's Response: Examiner appreciates applicant's amendment. The objection from the previous action is hereby withdrawn.

Drawing Objections

Summary of Argument: Applicant has submitted replacement drawing sheets which take care of the issues raised in the previous action. Applicant lists each issue and explains how it has been corrected (applicant's remarks pg. 16-17).

Examiner's Response: The examiner agrees. The previous drawing objections are hereby withdrawn.

37 CFR 1.75 Claim Objections

Summary of Argument: Applicant has amended claims 5 and 34 in order to overcome the objections under 37 CFR § 1.75(a) from the previous action. With regard to previous rejection to claims 1-34 under 37 CFR § 1.75(d)(1), the applicant provides clarification regarding the vague and indefinite term "predefined criteria", and argues that this objection should now be withdrawn.

Examiner's Response: With regard to the amended claims 5 and 34, the examiner appreciates applicant's amendment, and hereby withdraws the prior objection under 37 CFR § 1.75(a). With regard to claims 1-34, the examiner appreciates the further clarification that the applicant has provided regarding the term "predefined criteria". The claims objections under 37 CFR § 1.75(d)(1) is hereby withdrawn.

Prior Art Rejections

Summary of Argument: Applicant has amended independent claims 1 and 18 by adding the limitation of "executing a segmentation method that adaptively adjusts a segmentation threshold based on a local histogram analysis to determine an extent of the structural object in interest". This limitation was previously presented in claim 10. Applicant has cancelled claim 10, and added this limitation to claims 1 and 18. Applicant then argues that

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Armato III, et al (US 2002/0006216), which was used in the previous rejection of claim 10 to address this limitation, does not anticipate this claimed feature.

With regards to this claimed feature and the Armato reference. Applicant argues that the segmentation method disclosed in Armato does not adaptively adjust a threshold value based on a local histogram. Applicant argues that Armato uses a “multiple gray-level threshold technique”, which does not anticipate the newly added limitations to the claims. Applicant states that the Armato “multiple gray-level threshold technique” is not an adaptive adjustment, because Armato uses 36 pre-selected threshold values (applicant’s remarks pg. 20-21).

Examiner’s Response: Applicant’s arguments have been fully considered but are not persuasive. The Armato reference discloses identifying a single gray level in a histogram as the segmentation threshold. This identification and setting of a threshold value as disclosed in Armato qualifies as ‘adaptive adjustment’ of a threshold as recited in the claim. Applicant is reminded that claims are given their broadest reasonable interpretation (see MPEP § 2111). It follows that Armato, in selecting a single gray level as a threshold value, is adaptively adjusting the threshold. Applicant’s assertion that this is not an adaptive adjustment because the threshold values are one of 36 pre-set thresholds is irrelevant. The fact that there are finite possible threshold values does not preclude the selection of one of these values from being an “adaptive adjustment”.

The examiner would additionally like to point out that paragraph [0056] goes on to explain that an anterior junction line is automatically delineated (i.e. segmented) based on local maximum gray level information (i.e. local histogram analysis). Again, this clearly qualifies as an “adaptive adjustment”. The Armato reference plainly anticipates the added limitations.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 4-8, 11-13, 18, 19, 21-25, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Summers et al. (U.S. Patent No. 6,556,696 B1) and Kallergi et al. (U.S. Patent No. 6,630,937 B2), and further in combination with Armato et al. (U.S. Patent Application Publication No. US 2002/0006216 A1).

As applied to claim 1, Summers et al. disclose a computer-assisted diagnosis method for assisting diagnosis of anatomical structures in a digital volumetric medical image of at least one lung, comprising the steps of: identifying an anatomical structure of interest in the volumetric digital medical image (see Figs. 2 and 6 and column

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8, lines 1-6: The reference describes selecting a seed point to initialize the segmentation process. Therefore, this seed point identifies an anatomical structure of interest. The medical image data is also volumetric as can be seen in Fig. 6.).

Summers further discloses automatically segmenting, in real-time, the anatomical structure of interest in a predefined volume of interest (VOI) (see Fig. 8 and column 20, lines 41-44: The reference describes that in step 810 the process computes an isosurface of the anatomical structure depicted in the voxel data. This is equivalent to segmenting the anatomical structure of interest.).

Summers further discloses automatically computing, in real-time, quantitative measurements of the anatomical structure of interest (see column 17, line 44 – column 18, line 10: The reference describes computing the curvature (i.e. quantitative measurements) of the anatomical structure of interest.); displaying, in real-time, a result of said segmenting step (see Fig. 6 and column 7, lines 16-17: The reference describes that the 3D surface rendered model of the segmented anatomical region of interest is displayed as can be seen in Fig. 6.).

Summers further discloses estimating, in real-time, a likelihood that the anatomical structure of interest corresponds to a disease or an area warranting further investigation, based on predefined criteria and the quantitative measurements (see column 18, lines 11-40: The reference describes that lesions (i.e. a likelihood that the anatomical structure of interest corresponds to a disease or an area warranting further investigation) are determined based on the mean curvature (i.e. quantitative measurements) and size (i.e. predefined criteria).).

Summers further discloses generating, in real-time, a warning, when the likelihood is above a predefined threshold (see column 21, lines 3-11: The reference describes that based on the curvature characteristics, which were previously compared with a threshold value, a lesion on the surface of the anatomical structure of interest is colorized (i.e. generating a warning).).

Claim 1 further calls for the step of displaying a result of the computing step. While Summers et al. disclose displaying the anatomical region of interest and making measurements on that anatomical region of interest, the reference does not disclose displaying these quantitative measurements. However, Kallergi et al., in the same field of endeavor of medical image processing, and the same problem solving area of abnormality detection, disclose displaying a result of a computing step (see Fig. 8: As can be seen in the figure, a measurement of the diameter is displayed next to the anatomical area of interest (i.e. 1.44 cm).).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Summers et al. by displaying the results of the quantitative measurements and displaying a visual confidence bar as taught in Kallergi et al. because displaying such information would allow the system to be “as natural and intuitive to use by radiologists as possible” (see Kallergi et al.: column 2, lines 7-8). This information would allow radiologists to make a much more accurate diagnosis due to the extra information provided by the system.

Claim 1 further calls for the computing step to comprise the step of executing a segmentation method that adaptively adjusts segmentation thresholds based on local histogram analysis to determine an extent of the structural object of interest. The combination of Summers et al. and Kallergi et al. fails to disclose such a segmentation method. However, Armato et al., in the same field of endeavor of medical image processing and the same problem

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solving area of image segmentation, discloses a segmentation method that uses adaptive thresholds based on local histograms (see paragraph [0056]: The reference describes the use of a multiple gray-level thresholding technique applied a gray-level histogram of the area.).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the combination of Summers et al. and Kallergi et al. by adding the segmentation technique taught in Armato et al. because the use of such a segmentation technique is “a valuable aid to radiologists, thereby facilitating earlier diagnosis of lung cancer” (see Armato et al.: paragraph [0031]).

Therefore, it would have been obvious to combine Summers et al., Kallergi et al., and Armato et al. to obtain the invention as specified in claim 1.

With regard to claim 2, Kallergi et al. disclose that the generating step comprises the step of rendering a visual confidence bar (see column 6, lines 38-41: The reference describes displaying in a separate window the probability that an area of interest is malignant (i.e. a visual confidence bar)).

With regard to claim 4, Summers et al. disclose that the displaying step comprises the step of rendering a colored, three-dimensional representation of the anatomical structure of interest, with background structures, if any, rendered in contrasting colors with respect to the anatomical structure of interest (see column 21, lines 52-55: The reference describes a 3D modeling of the anatomical structure of interest where lesions are painted red and the background is colored a fleshy tone.).

With regard to claim 5, Summers et al. disclose that the quantitative measurements comprise a circularity of the anatomical structure of interest (see column 17, lines 44-49: The reference describes computing the curvature (i.e. circularity) of the anatomical structure of interest.).

With regard to claim 6, Kallergi et al. discloses that the identifying step is performed manually by a user (see column 6, lines 34-36: The reference describes that the user selects a region of interest (i.e. identifying step) by clicking with a mouse at the center of the region.).

With regard to claim 7, Summers et al. disclose that the identifying step is performed automatically (see column 8, lines 4-6: The reference describes that the process selects the seed points without any user intervention (i.e. automatically)).

With regard to claim 8, Summers et al. disclose that there is more than one anatomical structure of interest, and said method further comprises the step of repeating said segmenting, displaying, estimating, and generating steps, to examine each of the more than one anatomical structure of interest one of sequentially and randomly (see column 22, lines 10-15: The reference describes that the software cycles through and displays each lesion in a sequential order for the physicians examination.).

With regard to claim 11, Summers et al. disclose that segmenting and computing steps are performed substantially instantaneously (see Fig. 8: As can be seen in the figure, immediately after the structure is segmented 810, the curvature characteristics are calculated. Therefore, these steps are performed substantially instantaneously.).

Claims 12 and 13 call for a graphical user interface having a main window for displaying an axial view of the at least one lung. While Summers et al. discloses displaying the structure of interest, the reference does not

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expressly disclose a graphical user interface having a main window for displaying an axial view of the anatomical structure of interest. However, Kallergi et al., in the same field of endeavor of medical image processing, and the same problem solving area of abnormality detection, disclose such a graphical user interface (see Fig. 6).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Summers et al. by adding a graphical user interface as taught in Kallergi et al. because the addition of such a graphical user interface would "provide software that is as natural and intuitive to use by radiologists as possible" (see Kallergi et al.: column 2, lines 7-8).

Therefore, it would have been obvious to combine Summers et al. with Kallergi et al. to obtain the invention as specified in claims 12 and 13.

As applied to claims 18, 19, 21-25 and 31-33, which merely call for a system for performing the method claims, the combination of Summers et al. and Kallergi et al. discloses such a system as can be seen in Fig. 9 of Summers et al.

5. Claims 3 and 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Summers et al. (U.S. Patent No. 6,556,696 B1) and Kallergi et al. (U.S. Patent No. 6,630,937 B2), as applied to claim 1 in the rejection above, and further in combination with Spigelman et al. (U.S. Patent No. 6,119,033 A).

Claim 3 calls for the generating step to comprise the step of creating an audible signal. The combination of Summers et al. and Kallergi et al. only disclose generating visual signals during the generating step and do not expressly disclose generating an audible signal. However, Spigelman et al., in the same field of endeavor of medical imaging and the same problem solving area of abnormality detection, disclose producing an audible alarm when an object of interest is detected (see column 25, lines 58-65: The reference describes that an audible signal is provided when an object is detected in the image.).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the combination of Summers et al. and Kallergi et al. by adding the use of an audible alarm as taught in Spigelman et al. because if the signal is audible "the surgeon becomes aware ... even when the surgeon is not looking at the screen" (see Spigelman et al.: column 25, lines 63-65). This allows the doctor to more accurately determine whether a region is diseased or healthy.

Therefore, it would have been obvious to combine Summers et al., Kallergi et al., and Spigelman et al. to obtain the invention as specified in claim 3.

As applied to claims 20, which merely call for a system for performing the method of claim 3, the combination of Summers et al., Kallergi et al., and Spigelman et al. disclose such a system as can be seen in Fig. 9 of Summers et al.

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Allowable Subject Matter

6. Claim 34 is allowed.
7. Claims 9, 14-17, and 26-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick L Edwards whose telephone number is (703) 305-6301. The examiner can normally be reached on 8:30am - 5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Boudreau can be reached on (703) 305-4706. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

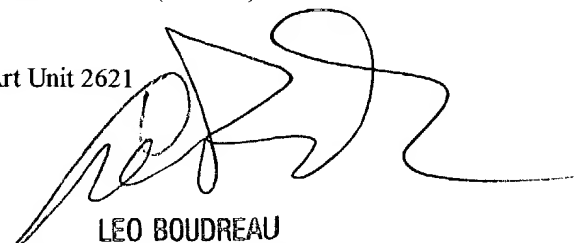
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Patrick L Edwards

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